

### **REMARKS**

Reconsideration of the allowability of the present application in view of the above claim amendments and the following remarks is respectfully requested.

#### **I. Status of the Claims**

Claims 23, 24, 32, and 34-40 were acted upon by the Examiner. Claim 35 has been canceled. Claims 23, 36, 38, and 40 have been amended. Accordingly, Claims 23, 24, 32, and 34, 36-40 are presented for examination.

#### **II. Summary of Examiner Interview**

Applicants wish to thank Examiners Kathleen Kerr Bragdon and Agnes Beata Rooke for taking the time to discuss the present application and the pending rejections with Applicants representative on June 26, 2008.

During the interview, after discussing the prosecuting history of the present application, the section 112 rejections (written description and enablement) and the anticipation rejections were discussed.

Regarding the section 112 rejections, in order to advance prosecution, Applicants representative agreed to amend Claim 23 to make clear that it is the fragment of SEQ ID NO: 2 that has the paralytic activity. Examiner Bragdon agreed that such an amendment should overcome the written description and enablement rejections.

Regarding the anticipation rejection, Applicants representative maintained that the current claim is not anticipated by the prior art, but, in order to advance prosecution, proposed to amend Claim 23 to recite an embodiment wherein the peptide is at least 90% pure. Examiner Bragdon agreed that this amended claim would not be anticipated.

#### **III. Discussion of Claim Amendments**

Claim 23 has been amended to add the recitations that the administered peptide comprises a fragment of at least 10 amino acids of SEQ ID NO:2 and that the fragment has paralytic activity. Support for this amendment can be found, for example, at page 8, lines 2-5.

Claim 23 has also been amended to recite that the peptide is purified at least 90%. Support for this amendment can be found, for example, in Claim 11 as originally filed. No new matter has been added.

Claim 36 was amended to recite that the peptide is purified at least 95%. Support for this amendment can be found, for example, in Claim 11 as originally filed. No new matter has been added.

Claims 38 was amended to correct a referencing error, and Claim 40 was amended for clarity. No new matter has been added.

#### **IV. Discussion of Objections**

The Examiner objected to Claim 38 as depending from Claim 1, which is canceled. As suggested by the Examiner, Claim 38 was amended to depend from Claim 23. Accordingly, this objection should be withdrawn.

The Examiner objected to Claim 40 as cumbersome. As suggested by the Examiner, Claim 40 has been amended to recite the mammal is a human. Accordingly, this objection should be withdrawn.

**V. Discussion of Section 112 Rejections**

**A. Indefiniteness Rejection**

The Examiner rejected Claim 36 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner objected to the use of multiple ranges in the claim. Applicants have amended Claim 36 to recite only a single range. Accordingly, this rejection should be withdrawn.

**B. Written Description/Enablement Rejection**

The Examiner rejected claims 23, 24, 32, 34-38 and 40 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description and enablement requirements.

As discussed above, the Examiner agreed to reconsider these rejections in view of the amendment to Claim 23 from which Claims 24, 32, 34-38 and 40 depend. During the Examiner Interview, the Examiners made clear that the claims were rejected because Claim 23 uses open language and thus may encompass additional amino acids in addition to the amino acids from SEQ ID NO:2, including other amino acids which provide a paralytic activity. As suggested by the Examiner and in order to advance prosecution, Applicants have amended Claim 23 to recite that it is the fragment of SEQ ID NO:2 of the claimed peptide that has paralytic activity.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

**VI. Discussion of Art Rejections**

**A. Novelty Rejection**

The Examiner rejected claims 23, 24, 32, 35, 38, and 39 under 35 U.S.C. § 102(b) as being anticipated by Bucherl et al. (Venomous Animals and their Venoms. Vol. 1, Academic Press, 1968). The Examiner asserts that on page 45, last paragraph, that Bucherl et al. teach that the purified toxin was concentrated, and with regards to mammals (i.e., rabbits), the lethal dose was determined. The Examiner also asserted that this toxin inherently includes the protein

sequence of SEQ ID NO:2 of the instant claims because the proteins originate from the same source and has the same function.

As required by 35 U.S.C. § 102(b) and explained in M.P.E.P. § 2131, [a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). M.P.E.P. § 2131.

As discussed above and suggested by the Examiners during the Examiner Interview, Claim 23 has been amended to recite that the peptide is purified at least 90%. As Bucherl et al. does not disclose a peptide at least 90% pure and that has paralytic activity, it cannot anticipate Claim 23 and its dependent claims. Accordingly, this rejection should be withdrawn.

#### **B. Obviousness Rejection**

The Examiner rejected Claims 23 and 34 under 35 USC 103(a) as being unpatentable as obvious over Bucherl et al. in view of Kohane et al. (US 6,326,020). The Examiner concedes that the teachings of Bucherl et al. do not teach a method of dosing a mammal in pain. The Examiner, however, asserts that Kohane et al. teach different nerve blockers that were used in animal models to make animals insensitive to pain. The Examiner further asserts that it would have been obvious to one skilled in the art to design a method where the paralytic peptide as taught by Bucherl et al. is administered to a mammal to alleviate pain.

Since as discussed above Buscherl et al. does not teach or suggest all the elements of Claim 23 as amended, such as the 90% purity recitation, even if Kohane et al. teaches using nerve blocker to treat pain (*arguendo*), its combination with Buscherl et al. does not render Claims 23 and 34 obvious. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

#### **VII. Conclusion**

In view of Applicant's claim amendments and the arguments presented above, the present application is believed to be in condition for allowance and an early notice thereof is earnestly

solicited. Applicants request that the Examiner contact the undersigned if there are any issues that prevent the allowance of the claims.

It is hereby requested that the term to respond to the Final Office Action dated March 14, 2008 be extended for one month, from June 14, 2008 to July 14, 2008. Payment to cover the extension fee is being submitted electronically. The Commissioner is hereby authorized to charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 19-5425.

Respectfully submitted,

/Marc S. Segal/  
Marc S. Segal  
Reg. No. 40,163

Synnestvedt & Lechner LLP  
1101 Market Street, Suite 2600  
Philadelphia, PA 19107  
Telephone: (215) 923-4466  
Facsimile: (215) 923-2189